

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	
_____	)	MDL NO. 1203
	)	
THIS DOCUMENT RELATES TO:	)	
	)	
SHEILA BROWN, et al.	)	
	)	CIVIL ACTION NO. 99-20593
v.	)	
	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J.

May 18, 2007

Teresa Tubbs ("Ms. Tubbs" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth, Inc.,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>2</sup>

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1. Prior to March 11, 2002, Wyeth, Inc. was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See (continued...)

To seek Matrix Benefits, a claimant must submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented.

In May 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician Michael J. Liston, M.D. Dr. Liston is no stranger to this litigation. According to the Trust, he signed 33 other Green Forms on the same date that he signed claimant's Green Form. As we have previously noted, in total he has signed more than 1,600 Green Forms on behalf of claimants seeking Matrix Benefits. See PTO No. 6339 at 3 (May 25, 2006). Based on an echocardiogram dated February 9, 2002, Dr. Liston attested in Part II of Ms. Tubbs' Green Form that she suffered from moderate mitral regurgitation and an

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2(...continued)

Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period, or who took the drugs for 60 days or less, or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

abnormal left atrial dimension. Based on such findings, claimant would be entitled to Matrix B-1,<sup>3</sup> Level II benefits in the amount of \$110,344.

In the report of claimant's echocardiogram, Dr. Liston stated that claimant's "mitral valve reveals moderate mitral insufficiency with the regurgitant jet measuring 23% of total left atrial dimension." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Liston also stated that claimant's "left atrium is mildly dilated measuring 4.1 cm in the parasternal view." The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id.

§ IV.B.2.c.(2)(b).

In October 2002, the Trust forwarded the claim for review by Waleed N. Irani, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Irani concluded that there was no reasonable medical basis for Dr. Liston's finding that claimant had moderate mitral regurgitation. According to Dr. Irani,

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3. Claimant ingested diet drugs for less than sixty-one days. Thus, if eligible for benefits, claimant only would be entitled to payment based on Matrix B-1. See Settlement Agreement § IV.B.2.d.(2)(b).

claimant had mild mitral regurgitation and her RJA was overestimated.<sup>4</sup>

Based on Dr. Irani's diagnosis of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Tubbs' claim. Pursuant to the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures"), claimant contested this adverse determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; Pretrial Order ("PTO") No. 2457, Audit Policies and Procedures § VI.<sup>5</sup> The Trust then applied to the court for issuance of an Order to show cause why Ms. Tubbs' claim should be paid. On April 8, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2826 (Apr. 8, 2003).

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4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Dr. Irani was not asked to review claimant's left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim. Thus, the only issue is claimant's level of mitral regurgitation.

5. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Rules for the Audit of Matrix Compensation Claims, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Policies and Procedures contained in PTO No. 2457 apply to Ms. Tubbs' claim.

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on May 2, 2006. Under the Audit Policies and Procedures, it is within the Special Master's discretion to appoint a Technical Advisor<sup>6</sup> to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Policies and Procedures § VI.J. The Special Master assigned Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant, and prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. Id. § VI.O.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. § VI.D. Ultimately, if we determine that there was no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such

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6. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

other relief as deemed appropriate. See id. § VI.Q. If, on the other hand, we determine that there was a reasonable medical basis, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id.

In support of her claim, Ms. Tubbs submitted a "Limited Fen-Phen Echocardiogram Study" prepared by Robert Rosenthal, M.D., along with Dr. Rosenthal's curriculum vitae.<sup>7</sup> Dr. Rosenthal also is no stranger to this litigation.<sup>8</sup> In his study, Dr. Rosenthal quantified claimant's RJA/LAA ratio as 23%.

In addition, claimant submitted a certification prepared by Dr. Rosenthal. In his certification, Dr. Rosenthal stated, in pertinent part, that:

The degree of mitral regurgitation is  $\geq 23\%$  with the maximal regurgitant jet of  $3.65 \text{ cm}^2$  documented at 12:12:04 recording time. This jet is measured conservatively by the sonographer and the area of the blue colored Doppler jet visualized is actually greater than  $3.65 \text{ cm}^2$ . As per Green Form appendix end notes #3 and #5, the maximal regurgitant jet is expressed as a percentage of the left atrial area. The jet is confirmed by [continuous wave] Doppler. Furthermore, the sonographer has specifically documented the presence and the extent of the mitral regurgitation using pulsed Doppler which confirms that the color jets are real and extend more than  $\frac{1}{2}$  the length of the left atrium. The auditing cardiologist may be

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7. We note that Dr. Rosenthal's "Limited Fen-Phen Echocardiogram Study" includes a disclaimer stating that: "[i]nterpretation of this study by the above named physician does not constitute a Doctor/Patient relationship."

8. The Trust submitted an affidavit, signed June 18, 2003, stating that Dr. Rosenthal had attested to 48 Green Forms as of May 31, 2003.

expressing his or her qualitative opinion of the degree of mitral regurgitation; however, the Settlement documents specify a scientific and quantitative degree of mitral regurgitation, a degree which is clearly substantiated by the echocardiogram.<sup>9</sup>

Claimant also argues that the phrase "reasonable medical basis" means that an attesting physician's conclusions must be accepted unless the Trust proves they were "irrational or senseless from any medical perspective" and that an opinion lacks a reasonable medical basis only when it is "so slanted" that it exists outside the "present state of science." Claimant further maintains that the auditing cardiologist did not follow the Settlement Agreement because he visually estimated her level of mitral regurgitation as opposed to taking actual measurements, which, in her view, are required by the Settlement Agreement.

In response, the Trust disputes claimant's characterization of the reasonable medical basis standard. Moreover, the Trust argues that the manner in which Dr. Irani evaluated claimant's level of regurgitation complied with the Settlement Agreement and claimant cannot meet her burden of proof simply by proffering an opinion from an additional cardiologist.<sup>10</sup>

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9. Dr. Rosenthal's study indicates that he reviewed claimant's echocardiogram on February 2, 2003. In his certification, however, Dr. Rosenthal stated that he reviewed her echocardiogram on April 14, 2003.

10. The Trust also argues that under Rule 26(a)(2) of the Federal Rules of Civil Procedure, physicians who proffer opinions regarding claims must disclose their compensation for reviewing  
(continued...)

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and determined that claimant had only very mild mitral regurgitation and that inaccurate measurements of the RJA and LAA were made. As explained by Dr. Vigilante:

In the parasternal long axis view, only trace mitral regurgitation was noted with just a few pixels of regurgitant flow immediately above the mitral leaflets in systole. In the apical two chamber view, trace mitral regurgitation again was noted with a very small jet only immediately above the mitral leaflets in systole. In the apical four chamber view, only very mild mitral regurgitation was noted with flow just slightly above the mitral leaflets during systole. This was quite obvious in "real-time" evaluation of the tape. The RJA/LAA was less than 10%. This very mild mitral regurgitation jet was seen in spite of the fact that there was excessive color gain noted in this study. Color artifact could be noted within the myocardium. The pulse wave doppler referred to by Dr. Rosenthal did not demonstrate high velocity turbulent flow more than half the length of the left atrium. In addition, the traced regurgitant jet area by the sonographer was found at recording time 13:32:25. This tracing was of a non-representative still frame and was not indicative of mitral regurgitation at all. Also, the tracing of the left atrial area was incorrect and did not include part of the posterior aspect of this chamber.

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10(...continued)  
claims and provide a list of cases in which they have served as experts. We disagree. We previously stated that Rule 26(a)(2) disclosures are not required under the Audit Policies and Procedures. See PTO No. 6997 (Feb. 26, 2007).



The Technical Advisor further stated that: "only very mild mitral regurgitation is present" and "inaccurate measurements of the RJA and LAA were made."<sup>11</sup>

After reviewing the entire Show Cause Record, we find claimant's arguments all without merit. First, and of crucial importance, claimant does not contest the analysis provided by Dr. Vigilante.<sup>12</sup> Nor does claimant challenge Dr. Vigilante's specific finding that the attesting physician relied on inaccurate tracings. Claimant also does not refute Dr. Vigilante's conclusion that "[i]t would be impossible for a reasonable echocardiographer to conclude that any more significant mitral regurgitation than mild was present on this study." On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

We also disagree with claimant's definition of reasonable medical basis. Claimant relies on Gallagher v. Latrobe Brewing Co., 31 F.R.D. 36 (W.D. Pa. 1962) and Black's Law Dictionary, 1379 (5th ed. 1979), for determining what constitutes a reasonable medical basis. Such reliance, however, is misplaced. In Gallagher, the court addressed the situation where

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11. The Technical Advisor also noted that he observed the name Dr. Mancina in the left upper corner of claimant's February 9, 2002 echocardiogram.

12. Despite an opportunity to do so, claimant did not submit any response to the Technical Advisor Report. See Audit Policies and Procedures § VI.N.

a court would appoint an impartial expert witness to be presented to the jury. See Gallagher, 31 F.R.D. at 38. Claimant also relies on the definition of "unreasonable" in Black's. The word "unreasonable" does not always mean "irrational" or "senseless," as claimant would have us believe. One of the definitions is "not guided by reason."

We are not persuaded that either Gallagher or Black's supports claimant's position. Instead, we are required to apply the standards delineated in the Settlement Agreement and the Audit Policies and Procedures. The context of these two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis. For example, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-15, 21-22, 26 (Nov. 14, 2002).

Here, the auditing cardiologist determined that claimant's echocardiogram revealed that her RJA was

overestimated. The Technical Advisor also concluded, and Ms. Tubbs does not dispute, that excessive color gain was observed on the echocardiogram, the traced RJA was of a non-representative still frame that did not represent mitral regurgitation, and the tracing of the LAA was inaccurate and included "part of the posterior aspect of the chamber." Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form answer of moderate mitral regurgitation.

Moreover, we disagree with claimant's arguments concerning the required method for evaluating a claimant's level of valvular regurgitation. Moderate mitral regurgitation is defined as "20%-40% RJA/LAA," which is based on the grading system required by the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having moderate mitral regurgitation, it does not specify that actual measurements must be made on an echocardiogram to determine the amount of a claimant's regurgitation. As we explained in PTO No. 2640, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." See PTO No. 2640 at 15.

While claimant relies on the Settlement Agreement's use of the word "measured" in the definition of "FDA Positive", its meaning must be considered in the context of the phrase "by an echocardiographic examination," which immediately follows it. See Settlement Agreement § I.22. In its entirety, the phrase

placed at issue by claimant is "measured by an echocardiographic examination." See id. The plain meaning of this phrase does not require actual measurements for assessing the level of mitral regurgitation. To the contrary, a claimant's level of regurgitation must be determined based on an echocardiogram, as opposed to other diagnostic techniques. Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements of mitral regurgitation be made to determine if a claimant qualifies for Matrix Benefits. There is no basis for such a revision and claimant's argument is contrary to the "eyeballing" standards we previously have evaluated and accepted in PTO No. 2640.

Finally, we are not persuaded by Dr. Rosenthal's certification that Ms. Tubbs' claim is medically reasonable. As stated by Dr. Rosenthal, his opinion is based on one maximal jet, which he believes is confirmed by continuous wave Doppler. For a reasonable medical basis to exist, a claimant must demonstrate that his or her regurgitation is representative of the level of regurgitation seen on an echocardiogram.<sup>13</sup> To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement. Additionally, it is

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13. Under the Settlement Agreement, moderate or greater mitral regurgitation is defined as a "regurgitant jet area in any apical view equal to or greater than twenty percent (20%) of the left atrial area (RJA/LAA)." Settlement Agreement § I.22. Nothing in the Settlement Agreement suggests that it is permissible for a claimant to rely on isolated instances of what appears to be the requisite level of regurgitation to meet this definition.

improper to rely on continuous wave Doppler to support a finding of regurgitation. As we stated in PTO No. 2640, "[n]owhere does the Green Form authorize the use of continuous wave Doppler to establish the severity or duration of mitral regurgitation." PTO No. 2640 at 18.

For the foregoing reasons, we conclude that claimant has not met her burden in proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Tubbs' claim for Matrix Benefits.

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**PRETRIAL ORDER NO.**

AND NOW, on this 18th day of May, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the post-audit determination of the AHP Settlement Trust is AFFIRMED and the Level II Matrix claim submitted by claimant Teresa Tubbs is DENIED.

BY THE COURT:

/s/ Harvey Bartle III

C.J.